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Assessment of the Noise Immune Stethoscope in a Clinical Environment

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14. ABSTRACT

This study was conducted in support of advanced technology development for clinical auscultation in high noise environments. The diagnostic performance of the Noise Immune Stethoscope (NIS) was assessed by user-clinicians in a low noise clinical environment. The NIS is a hybrid dual function stethoscope with both electromechanical acoustic (passive) and ultrasound Doppler (active) modes. Data were collected by four clinicians including a nurse, two ER physicians, and a flight surgeon. A total of 50 observations were made with both modes for cases of adventitious cardiopulmonary sounds and to assess hemo/pneumothorax. Overall, users evaluated the device to be moderately helpful in making clinical diagnosis and decisions compared to a traditional stethoscope. In agreement with prior reports, participants expressed difficulty with the Doppler mode but rated their confidence in ability to make diagnoses in the acoustic mode favorably. Recommendations for improvement are discussed.

15. SUBJECT TERMS

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Introduction

Cardiac and pulmonary sounds cannot be auscultated in a high noise environment, such as an operating helicopter. To provide clinicians a means of auscultation in the austere environment, a novel approach to stethoscope design, using ultrasound, has been developed (e.g., Active Signal Technology). The Noise Immune Stethoscope (NIS) is a hybrid, dual mode stethoscope device with both electromechanical acoustic (passive) and ultrasound Doppler (active) modes (see appendix A for technical specifications). It is designed specifically to defeat noise and preserve signal-to-noise ratios (SNR). This permits clinical auscultation in moderate to severe background noise conditions which could improve ability to diagnose and subsequently provide medical intervention across the spectrum of care from point of injury through evacuation and levels of care. Furthermore, the novel integrated Doppler carrier wave design may present to health care providers unique ultrasound diagnostic information not readily available with a traditional stethoscope.

Testing and evaluation of the NIS prototype devices to date have verified the ability of the stethoscope to function (preserve SNR) in high ambient noise conditions. However, this testing has only included small numbers of clinicians and small numbers of test subjects (e.g., Gaydos, Williams, Reeves, and Kelley, 2010). What remains unknown is the diagnostic potential of the NIS under conditions of human pathophysiology (e.g., pneumothorax, hemothorax, thoracic trauma, pneumonia, arrhythmias, valvulopathy, heart failure, endotracheal tube misplacement). Future evaluation strategy and research must include qualitative diagnostic assessment of the stethoscope's effectiveness by a clinician cohort representative of future end-user clinicians (e.g., trauma physicians, physician assistants, nurses, medics, flight surgeons and flight medics, internists).

Background

Clinical examination by auscultation with a stethoscope is fundamental to the assessment of patients; it is rapid, simple, portable, and can be readily repeated to assess patient physiologic status. Meaningful auscultation is compromised, however, in high ambient noise environments.

The asymmetric battlefield of today requires immediate and definitive care of wounded Soldiers, even in conditions of high background noise. This care can include rapid diagnosis, monitoring, and intervention for life-threatening injuries anywhere from the point of injury through evacuation and multiple levels of care. For medical providers delivering this care, examination and clinical decision-making using auscultation is a vital tool. Yet, traditional bell and diaphragm stethoscopes are inadequate for auscultation in high ambient noise environments such as a medical evacuation helicopter (e.g., 110 decibels [dB] in a UH-60 model).

Noise can contaminate the auscultation system of a stethoscope through several routes: via transmitted surface waves across the patient's skin, through the housing of the head of the device or rubber tubing, or penetrating the interface of the earpiece and external ear canal. Recent solutions to improve clarity and subsequent diagnostic yield of stethoscopes in conditions of noise have included the “electronic” stethoscope, whereby a microphone in the headpiece converts sound waves into electrical energy negating the need for rubber tubing. These devices can also serve to amplify the signal and, in some cases, include digital signal processing. However, the desired signals corresponding to physiologic patient sounds often lie within the spectrum of ambient noise or background noise—simple amplification in the acoustic mode of a traditional stethoscope indiscriminately affects both signal and noise, whereas filtering of the ambient noise can interfere with detecting cardiac rhythm and respirations (Ahroon, Houtsma, & Curry, 2007).

Furthermore, none of these solutions allow for auscultation in severe ambient noise (>90dB). There exists a need for a device capable of adequate signal-to-noise ratios and sound discrimination under high noise conditions common in austere military conditions. Under the provisions of a Small Business Innovative Research (SBIR) award, Active Signals Technology (AST, Inc.) of Linthicum Heights, Maryland, in conjunction with the U.S. Army Aeromedical Research Laboratory (USAARL), developed a "noise-immune" stethoscope (NIS) to address this need (Sewell, 2006).

The NIS device consists of a unified hybrid dual-mode design including both an electromechanical acoustic (passive) mode and a 2 to 3 mega-hertz (MHz) ultrasound Doppler (active) mode. The enhanced acoustic mode functions similarly to an electronic stethoscope, but consists of a directly coupled piezoelectric ceramic stack instead of a simple microphone ensemble. The integrated active mode consists of a Doppler ultrasound transmitter carrier wave with a receiver-transducer integrated into the stethoscope's head. The carrier wave, reflected back off of patient tissue, is modulated by the Doppler Effect (e.g., when auscultating the heart, if the cardiac wall motion is moving towards the receiver, the wave reflected back to the receiver is at a higher frequency) generating an audible signal return for the clinician to hear. The advantage of this technology is essential "immunity" to ambient noise invasion, since environmental noise does not interfere with sound at such a high frequency (Houtsma, Curry, Sewell, & Bernhard, 2007).

Representative samples of digital recordings, from the NIS, of cardiac sounds in ambient noise conditions are depicted in figures 1 through 4. Note that the heartbeat physiologic signal is preserved among background noise at 70 dB for the acoustic mode, but lost at the extreme 110 dB range. The cardiac sounds are preserved at 110 dB of noise for the Doppler mode (Gaydos et al., 2010).

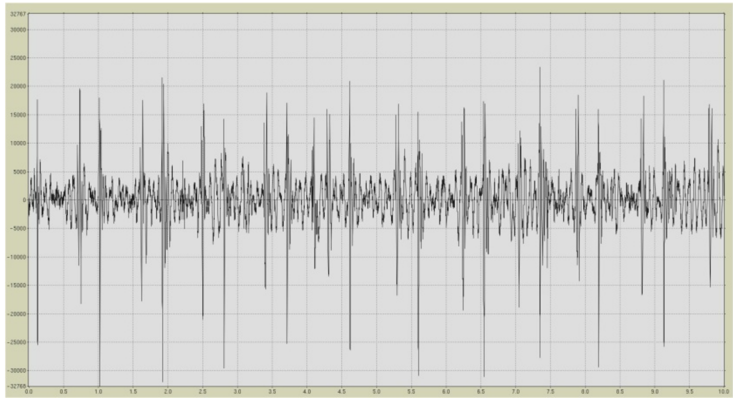

*Figure 1. Heart sounds, acoustic mode, 70 dB.

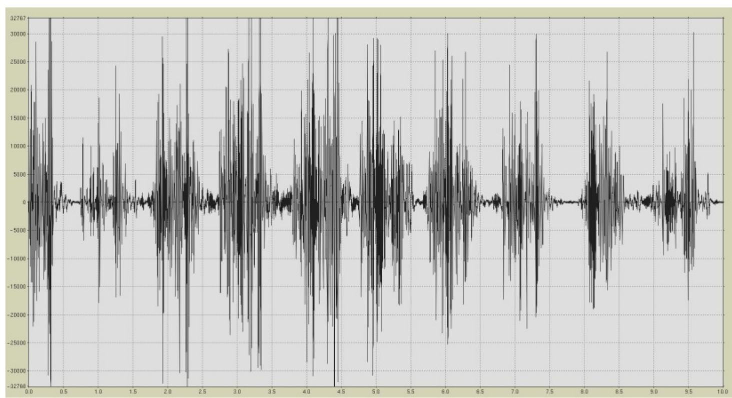

*Figure 2. Heart sounds, Doppler mode, 70 dB.

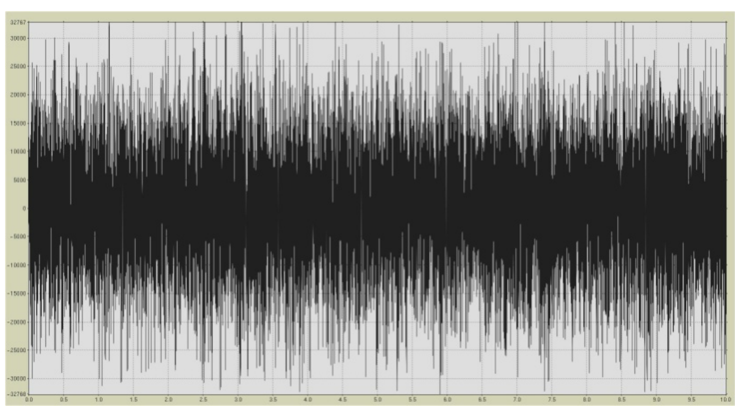

*Figure 3. Heart sounds, acoustic mode, 110 dB.

*Note: Digital recordings were made and analyzed using Graphical Interactive Processing of Speech (GIPOS, ver. 2.3) software.

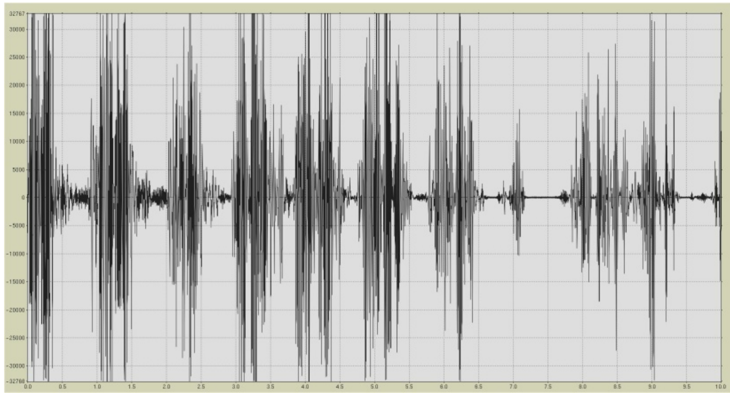

*Figure 4. Heart sounds, Doppler mode, 110 dB.

The NIS device, pictured in figure 5, is designed for one-handed operation (including a gloved hand with aviation Nomex) with the operator controlling the neck of the NIS between the index and middle fingers. Above the single, hand-held position is the head of the NIS which houses the batteries. Below the single, hand-held position is the body of the NIS that makes skin contact with the patient in order to hear the appropriate cardio-pulmonary sounds in either the acoustic or Doppler mode. The NIS is operated via a four-button thumb control: acoustic mode and Doppler mode “on” switches, as well as volume increase/decrease switches, and a 10-minute automatic timed shut-off. The device is powered by two 1.5 V AA-cell batteries located in the stethoscope's headpiece. The coaxial cable electrical output of the device can be configured for use with headset ear phones or to be compatible with the Army's HGU-56/P Aircrew Integrated Helmet System with Communications Ear Plugs (CEPs) for both hearing protection and auscultation. The Doppler mode requires the use of standard ultrasound contact gel between the stethoscope and the patient's skin to minimize reflections at this boundary layer.

Figure 5. Prototype of dual-mode NIS depicting one-handed operation, four-button thumb control: acoustic and Doppler mode “on” switches, volume control, and a 10-minute automatic timed shut-off, and a coaxial cable electrical output. (Photos courtesy of Active Signal Technologies, Inc., Linthicum Heights, Maryland)

It should be noted that the audible returns of the ultrasound Doppler (active) mode are distinctly different from that of a traditional stethoscope. For example, Doppler heartbeat sounds have been described as a “ta-dá-da” three-part rhythm pattern versus the “lub-dub” of a traditional stethoscope (Houtsma et al., 2007). Yet one has the ability to discern different sounds. In a pilot study (Mc Loughlin et al., 2012), a continuous wave Doppler (CWD) that produced sounds but no images was informative in detecting cardiac pathophysiology [123/193 cases, 63.7%] in contrast to using a traditional stethoscope [76/193 cases, 39.4%] by which color Doppler echocardiography (CDE) validated all cardiac anomalies. This insight suggests that with a novel dual mode stethoscope, one has the capability to detect sounds. Thus, clinicians can be trained to recognize and interpret these novel cardiac and pulmonary sounds from the NIS, just as they are trained to recognize and interpret cardiac and pulmonary sounds from a traditional stethoscope.

A finalized product device would likely be accompanied by an educational “push-package” (possibly in the form of a compact disk and potential hands-on instruction from a skilled trainer) when fielded to “end-user” clinicians (Brady, 2009). The “push-package” would include, among other things, sound recordings and information that will serve to “re-train” clinicians as to typical or expected sounds corresponding with auscultation of human physiology (e.g., cardiac rhythm and respirations) when using the ultrasound Doppler (active) mode of the NIS.

USAARL initially conducted preliminary and developmental testing of the advanced prototype NIS device in a reverberant sound chamber which demonstrated that the acoustic mode functioned (preserved a SNR ratio > 0) to an ambient noise environment of approximately 90 dB, whereas the Doppler mode maintained SNRs of approximately 20 dB up to 110 dB of ambient noise (Houtsma, Curry, Sewell, & Bernhard, 2006). Subsequent tests in flight confirmed the ability to auscultate both cardiac and pulmonary sounds using the Doppler mode in a UH-60 helicopter (Houtsma & Curry, 2007). In addition, the Doppler mode proved somewhat problematic in detecting iatrogenic pulmonary pathology (e.g., incremental hemothorax and/or pneumothorax) when used on swine possibly due to the inability to regulate inspiration and expiration on command in animals (Bushby et al., 2011). The authors noted poor specificity for injury, though it is unclear if the performance of the NIS was affected by lack of operator training, poor operator technique, and/or technical shortcomings of the novel device.

Advanced prototypes have undergone several revisions and technical improvements (Sewell & Cooke, 2009). Specific technical revisions to the advanced prototypes have included the following:

a. The diaphragm's rubberized O-rings were replaced with the addition of a machined ridge.
b. The diaphragm surface was modified from a metal-plastic hybrid to an acrylonitrile butadiene styrene (ABS) plastic “across-the-face” plate.
c. The impedance-matching hardware was replaced with a directly coupled piezoelectric stack.
d. The syntactic foam was removed from the posterior side of the Doppler element.
e. The transmission power of the Doppler was increased from beyond ambient noise to 2 to 3 MHz.
f. A low-pass 500 Hz filter for the acoustic mode was added.

Follow-up testing of the production model NIS was conducted in the reverberation chamber at USAARL (Gaydos et al., 2010). Quantitative evaluation confirmed preservation of SNR > 0 to 90 dB of ambient noise for heart sounds and 100 dB for breath sounds in the acoustic mode. The Doppler mode preserved SNR of 20 to 110 dB (testing limit) for both cardiac sounds and respirations. An example of mean SNR recordings for heart sounds in high ambient noise is depicted in figure 6.

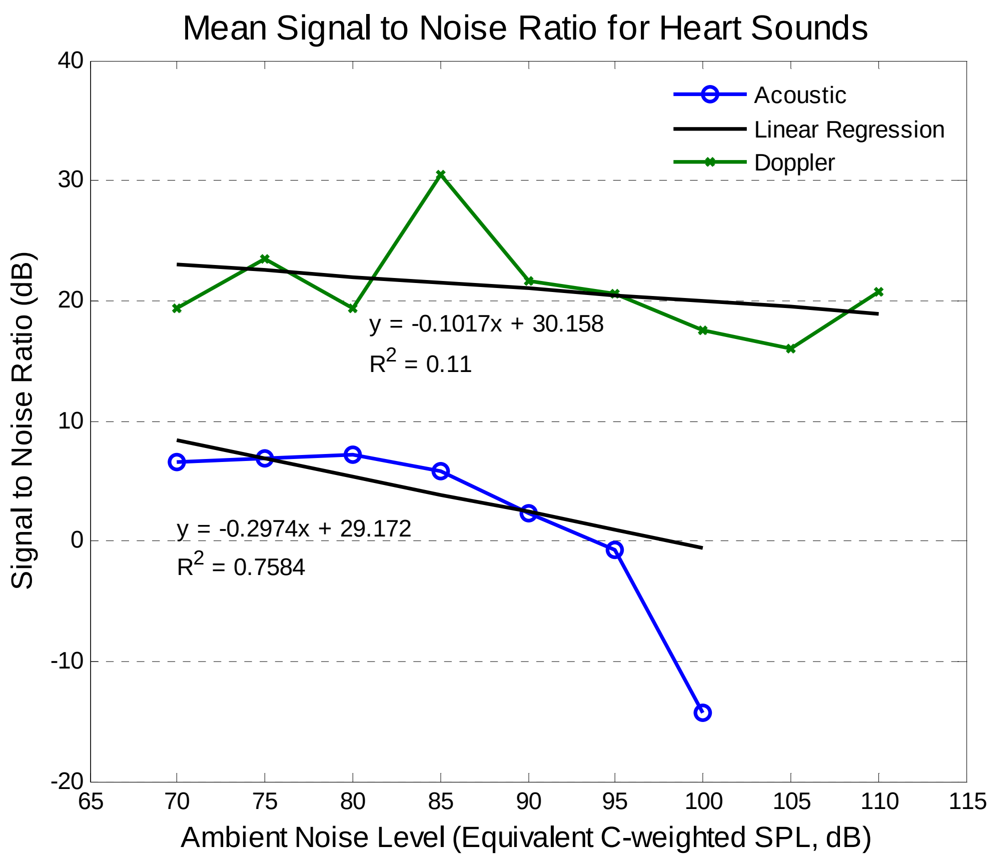

Figure 6. Mean SNR versus ambient noise level (C-weighted dB SPL) for cardiac sounds. (Note: Heartbeat signals were not audibly discernable at or above 100 dB in the acoustic mode.) (Gaydos et al., 2010)

Gaydos et al. (2010) also included in their evaluation of the NIS a qualitative assessment consisting of a convenience sample of five representative "end-user" clinicians who evaluated the device at 70, 90, and 110 dB. Clinical usefulness of the signal for normal physiologic cardiac rhythm and respirations was determined to be at least "fair" at 70 and 90 dB for acoustic (passive) mode and 70, 90, and 110 dB in the ultrasound Doppler (active) mode when listening to cardiac rhythm and respirations. They pointed out that the NIS should be positioned at the left of the sternum along the fourth intercostal space at which the apex of the heart has its loudest sound. As for listening to respirations, the ideal position of the NIS is situated within the mid-axillary of the patient.

As mentioned, the audible returns for the Doppler mode, while defeating extreme ambient noise environments, are distinctly different than that of a traditional bell and diaphragm stethoscope. Although clinicians would require training to become accustomed to the novel cardiac rhythm and respirations when heard in the ultrasound Doppler (active) mode of the NIS, the device may also represent a unique and portable, bedside diagnostic device in contrast to the larger, non-portable ultrasound machines. The Doppler signal does carry ultrasound returns undetectable using a traditional stethoscope, perhaps containing *novel* clinical information

(Houtsma et al., 2007). Therefore, ultrasound Doppler cardiac rhythm and respirations may be of use to internists, intensivists, or cardiologists even in quiet conditions provided these unique returns are correlated to specific abnormal physiology. This represents a second important potential application for the NIS device.

Testing and evaluation of the NIS prototype devices to date have verified the ability to function (preserve SNR) in high ambient noise conditions and provide clinically useful information. However, this testing only evaluated the effectiveness of the NIS used by a handful of clinicians when assessing normal physiologic sounds. The current study was intended to focus on a larger-scale qualitative diagnostic assessment of the effectiveness of the NIS with a representative cohort of potential "end-user" clinicians trying to determine a variety of *human pathophysiology*, e.g. cardiac and pulmonary anomalies.

Methods

This study was conducted at a large military teaching hospital (Madigan Army Medical Center) using a prospective, non-randomized qualitative survey. Data collection was conducted by clinicians and health care providers enrolled in the study as observers (clinician-participants).

This study was approved by IRB's at Madigan Army Medical Center and Medical Research and Materiel Command. Data collection was strictly supplemental to patient care; patient diagnosis and medical treatment were never delayed or otherwise compromised due to the study. The NIS was used only after the required initial triage, diagnostic, and stabilization measures were provided to the patient in accordance with established conventional medical and/or surgical practices.

Clinicians at two locations were trained by AST, Inc. to use the NIS. The first training session took place at the U.S. Army Aeromedical Research Laboratory at Fort Rucker, AL where AST, Inc. educated two flight surgeons who practiced using the device in a "noise free" environment, followed in a noise chamber exposed to 90 to 110 dB, and then on-board a UH-60 aircraft. The second training session was conducted at Fort Lewis, WA within Madigan Army Medical Center. The Madigan clinicians received the same academic background and educational usage of the NIS by AST, Inc. They also practiced with the NIS on each other with the assistance of one of the flight surgeons, previously trained by AST, Inc. and associates at USAARL.

Participants

Initially, fifteen clinicians enrolled in the study, however only four of those clinicians (a nurse, two resident emergency room [ER] physicians, and one flight surgeon) participated in the study. A total of 47 patients (mean age of 61.7 years [ranging from 21 to 92 years of age]; 3 patients' ages were not reported on the survey), 16 female and 25 male (6 patients' gender not reported) gave consent to being evaluated by the clinician, resulting in 50 independent clinician observations made with the NIS. Two observations were made by a nurse, 16 observations were made by one resident ER physician, 6 made by the other resident ER physician, and 26 made by the flight surgeon. Of the 47 patients who were assessed with the NIS, 18 presented with cardiac related pathology and the remaining 29 presented with pulmonary pathology. All patients were stable at the time of being consented by the clinician and none of the data collected contributed to identifying new pathology or diagnosing a pre-existing condition.

Procedure

Within the Madigan Army Medical Center, patients are located on various floors dependent on the type of medical management. On each floor are a team of physicians, nurses and technicians that manage the patients. Prior to briefing, explaining, and consenting to the patients, the head nurse on each ward (e.g., internal medicine, family medicine, surgical, ICU, ER) was given a courtesy overview of the NIS. Once approved by the head nurse, potential participants were identified from a chart within each main station on the floor which gave the name, room number and diagnosis.

Observations made by clinicians assessing the NIS focused on three medically related physical conditions: intubation integrity, hemo/pneumothorax, and adventitious/pathologic cardiac sounds and respirations. Twenty-one observations were made in the ER, 24 observations gathered from the in-patient family medicine floor and in-patient internal medicine floor combined, 1 from the intensive care unit, and 1 from the surgical floor (3 observation locations were not reported). The assessment made by the clinician was through auscultation of cardiac sounds and respirations using the NIS, and completion of the data collection form by the clinician (appendix B). The data collection form focused on three conditions: intubation integrity, hemo/pneumothorax, and adventitious/pathologic heart and lung sounds. Qualitative scoring was based on a 7-point Likert scale ranging from 1 (poor) to 7 (excellent) with sections available for the clinician to make general comments and observations. Data were collected and sent back to USAARL where the NIS project team collated and formatted the data for analysis using SPSS software.

Results

Intubation integrity

There were no observations made to assess intubation integrity.

Pulmonary pathology: Hemothorax and pneumothorax

Clinicians made assessments on three different patients with a hemothorax and/or pneumothorax using the NIS within the Emergency Department and surgical floor. Prior to the use of the NIS, confirmatory diagnosis methods included chest x-ray and ultrasound. A Wilcoxin rank-sum test indicated that clinicians similarly rated their *ability* to auscultate respirations in a naïve patient as compared to a patient with decreased or absent respirations attributed as a result of a known hemothorax and/or pneumothorax, using the NIS device to assess the pathology in both the acoustic and Doppler mode, $Z = -1.00$, $p = 0.317$. Clinicians also rated their *confidence* in using the NIS versus a traditional stethoscope when assessing a patient to make the correct diagnosis. Ratings of *confidence* between the acoustic mode and Doppler mode of the NIS were not significantly different as confirmed by a Wilcoxin rank-sum test, $Z = -1.342$, $p = 0.180$ (figure 7).

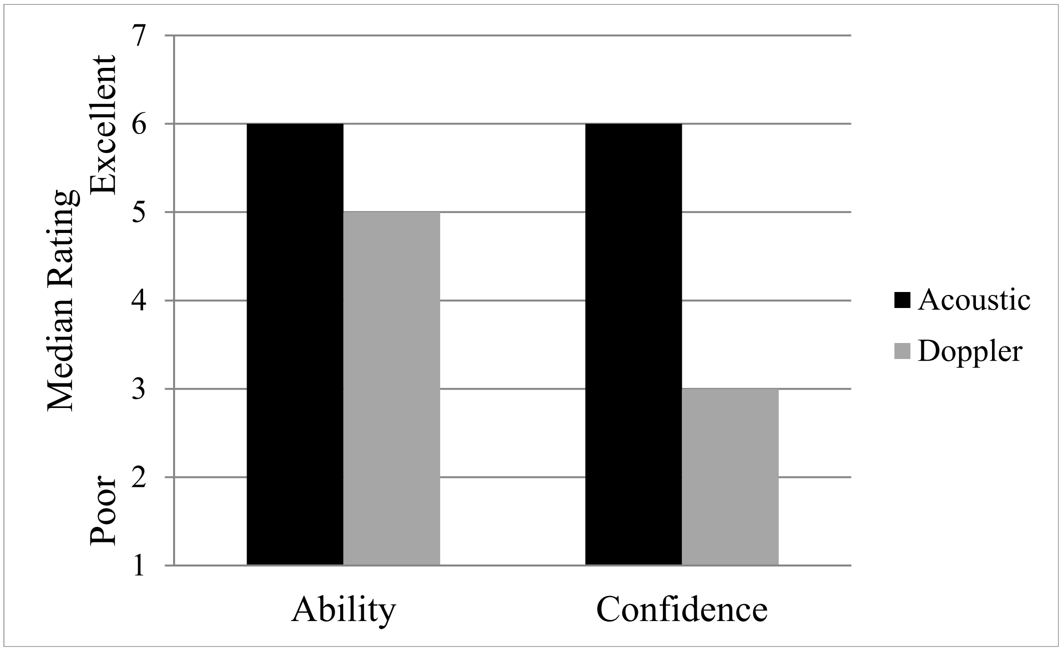

Figure 7. Median ratings of one's ability to detect respirations using the NIS as well as the confidence in the device to correctly identify sounds in both acoustic and Doppler modes (median for both ability and confidence in the Acoustic mode is 6). Note that the scale ranged from 1 (poor) to 7 (excellent).

General pathology: Cardiopulmonary

Clinicians made a total of 47 assessments on patients while using the NIS when determining adventitious or pathologic cardiac and pulmonary sounds. Diagnoses included pneumonia, pulmonic stenosis, mitral regurgitation, emphysema, congestive heart failure, acute asthma, and aortic stenosis (table). Confirmatory diagnosis methods included chest x-ray, computed tomography (CT scan), cardiac catheterization, and formal ultrasound. Clinicians rated their confidence in their usage of the NIS, as compared to a traditional stethoscope, to detect cardiac sounds and respirations. Clinicians rated their *confidence* in the use and their *ability* to detect sounds with the NIS as greater in the acoustic mode (passive) than in the Doppler mode (active) as confirmed by a Wilcoxin rank-sum test, $Z = -5.807$, $p < 0.001$ (figure 8). Comments with respect to sound unique to each diagnosis are presented in appendix C.

Table.
Frequency and percentages of diagnoses and detection when using the NIS.

Diagnosis	Frequency	Percent (%)
Aortic stenosis	12	25.53
Pneumonia	9	19.15
Congestive heart failure (CHF)	7	14.89
Acute asthma	6	12.77
Aortic regurgitation	2	4.26
Chronic obstructive pulmonary disease	2	4.26
Mitral regurgitation	2	4.26
Pneumonia/CHF	2	4.26
Emphysema	1	2.13
Gun-shot wound/lung collapse	1	2.13
Heart murmur	1	2.13
Artificial mitral valve	1	2.13
Pneumonia/history of ischemia	1	2.13
Pulmonic stenosis	1	2.13

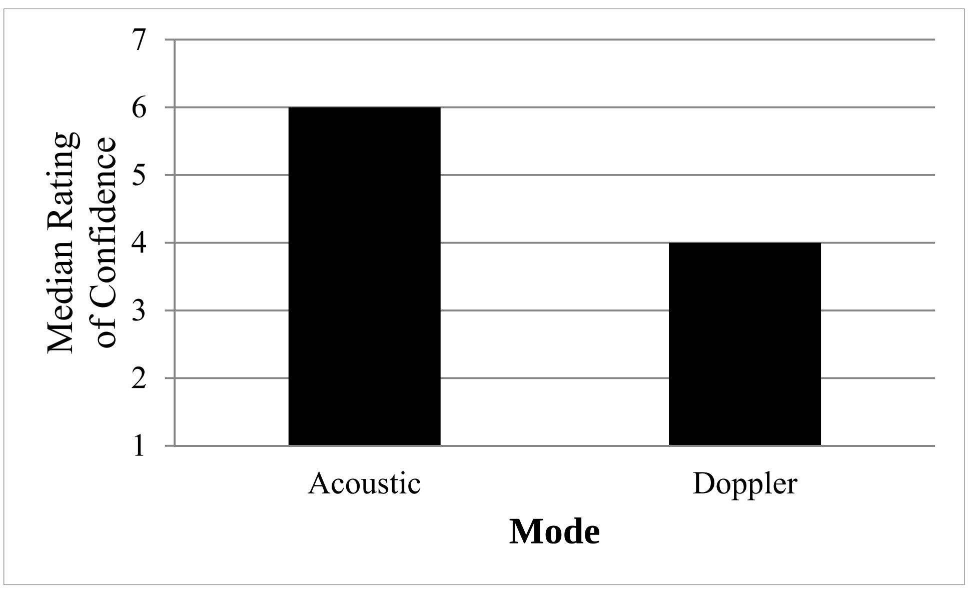

Figure 8. Median ratings in clinician confidence in using the NIS in both acoustic and Doppler modes to detect cardiopulmonary sounds versus a traditional stethoscope. Note that the scale ranged from 1 (poor) to 7 (excellent).

Ease of use

Clinicians were asked to rate, on a scale of 1 (difficult) to 7 (easy), the ease of use of the NIS, as compared to a traditional stethoscope. A Wilcoxin rank-sum test indicated that clinicians rated use easier in the acoustic mode of the NIS than in the Doppler mode of the NIS, $Z = -5.49$, $p < 0.001$. A Mann-Whitney *U* test indicated no significant differences between rated ease of use between the conditions (hemothorax and/or pneumothorax versus cardiopulmonary sounds; figure 9). To assess the ease of use of the NIS, as compared to a traditional stethoscope, a one-sample Wilcoxin signed rank test was conducted. The results indicated that in the acoustic mode, clinicians rated the device to be easier to use than a traditional stethoscope, $Z = 5.397$, $p < 0.001$. The test revealed non-significant results for the Doppler mode.

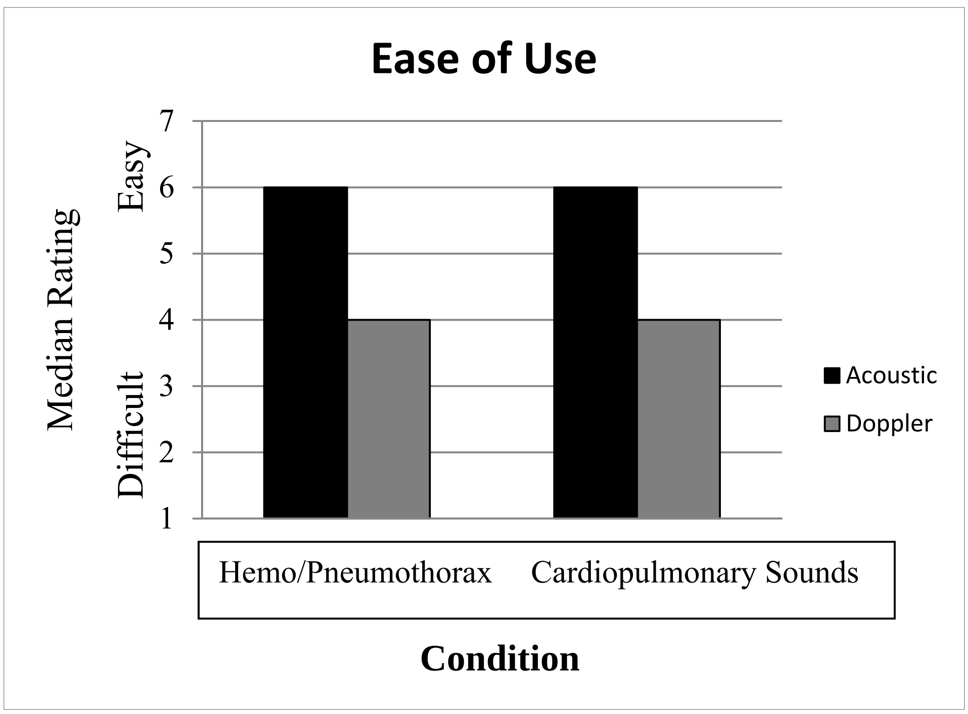

Figure 9. Median ratings of ease of use of the NIS separated by condition and mode. Note that the scale ranged from 1 (difficult) to 7 (easy).

Clinicians rated their impressions on the necessity for three different training methods (self-taught, instructional CD, “hands-on” training) when using the NIS on a scale from 1 (no) to 7 (yes). Mann-Whitney *U* tests indicated non-significant results for comparison of ratings of necessity for all training methods. However, there were significant differences between the rated necessities of the three training methods (based on Friedman’s 2-way ANOVA by ranks test, $X^2 = 17.85$, $p < 0.001$). Subsequent comparisons (Friedman’s pairwise) indicated that participants rated the training methods of a teaching CD or hands-on learning as a necessity over the option of self-teaching (figure 10).

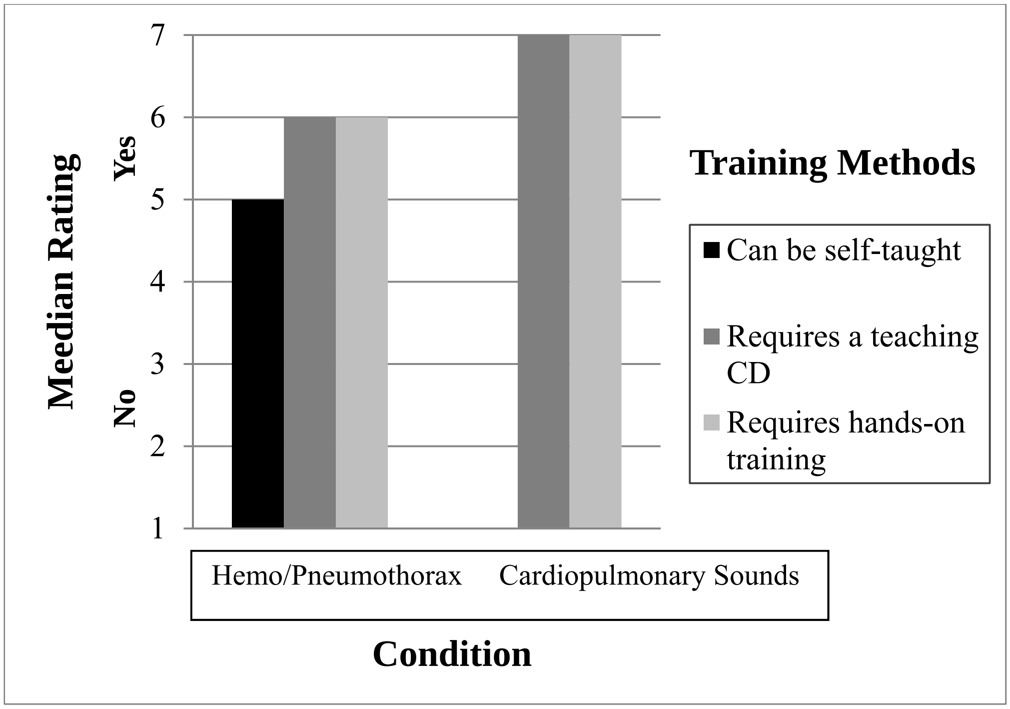

Figure 10. Median ratings of necessity for three different training methods. Note that the scale ranged from 1 (no) to 7 (yes).

Clinicians were asked to rate on a scale of 1 (problem) to 7 (easy) the degree to which they felt the requirement of ultrasound gel in the Doppler mode was problematic. A Mann-Whitney *U* test indicated no significant difference between the ratings of the gel in the cardiopulmonary sounds conditions versus the hemothorax and/or pneumothorax condition (figure 11).

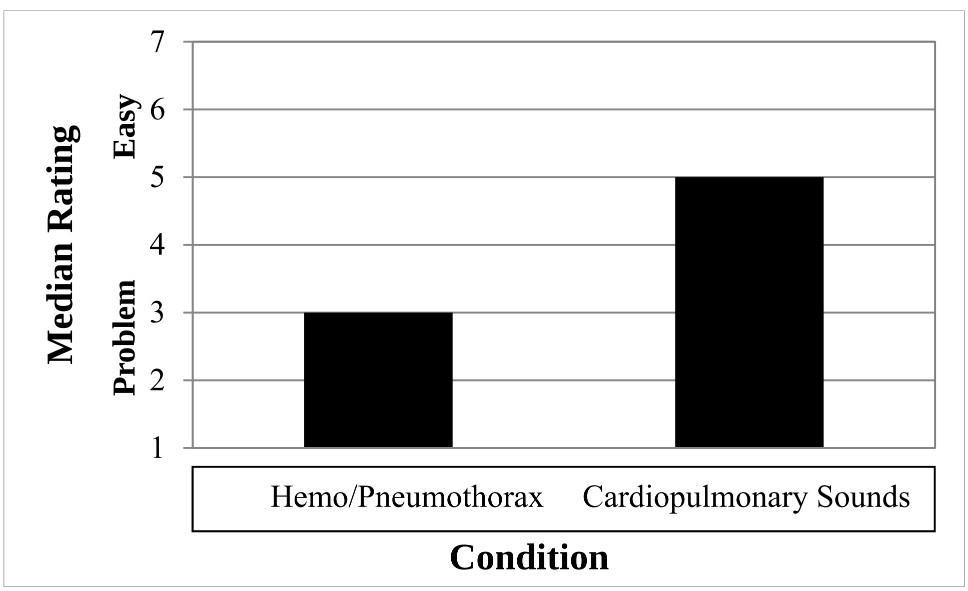

Figure 11. Median ratings of whether the requirement of ultrasound gel was problematic. Note that the scale ranged from 1 (problem) to 7 (easy).

Discussion

The objective of this study was to assess the NIS in a clinical environment. This study follows a similar effort, which found that clinicians rated the acoustic mode of the NIS favorably and as easy to use as a traditional stethoscope (Gaydos et al., 2011) in a high noise clinical environment (aboard a naval carrier). However, clinicians reported the Doppler mode of the NIS to be difficult to use and rated this mode less favorably than the acoustic mode. The results of the present study agree with these previous findings. Many challenges faced in the naval carrier study were similar in the present study. These challenges included difficulties with operating the NIS, the number and type of personnel involved, limitations in training on the NIS and the instructional DVD, and the types of observations made in both the acoustic (passive) and ultrasound Doppler (active) mode. However, the present study yielded further insights into clinicians' understanding and operating of the NIS. Whereas the prior study captured clinicians operating in a real-world deployed military environment with limited types of medical cases, this study was designed to capture clinicians managing patients in a large scale medical treatment facility with greater variety in medical pathophysiology.

The clinicians in the present study reported a positive ability to detect and with increased confidence to hear cardiopulmonary sounds in the acoustic mode far greater than in the ultrasound Doppler (active) mode. The training DVD makes it clear that due to the unique attributes of the NIS, the design of the model is limited in translating respirations as lung movements, e.g., the coarse sound of sandpaper on a hard surface. It is important to note that true respirations heard via the acoustic and Doppler modes of the NIS do not equate to the sounds that one is accustomed to hearing with a traditional stethoscope. Moreover, the challenge of listening to respirations as translated in the Doppler mode must compete against external factors such as external vibration or the coarse sound that follows with placing the NIS on the body. For example, one provider noted the ease of hearing pulmonary "crackles" in the acoustic mode but noticed a different "deep rumbling like thunder" in the Doppler mode. In another survey, pulmonary pathologic "clicks" associated with rales were interpreted as sounding "duller." In the above examples, "clicks" and "crackles" are sounds associated with pulmonary disease and are collectively called rales. Lastly, the location of an infiltrate, secondary to a pulmonary infection associated with pneumonia, determined by a chest x-ray and CT scan, was only appreciated as no sound within the affected region of the lung. If success is defined by a simple yes/no response as to the detection of lung movement, then the NIS is a success. However, if success is defined by identifying/diagnosing/trending the patient's medical condition, then this conclusion is still premature. Overall, the ease of the acoustic mode was attributable to a minimal learning curve when locating and hearing the appropriate sounds/movements, while the Doppler mode challenged clinicians probably due to the unfamiliar sounds and landmarks involved.

As recommended by the instructional DVD, the NIS is placed at the apex of the heart which is located left of the sternum within the fourth left intercostal space (4LICS, figure 12). Ease of use and confidence in using the acoustic mode and the Doppler mode resulted in "equal to" and "above" efficiency as compared to using a traditional stethoscope. Anecdotal feedback from the clinicians indicated that sounds from the heart and related cardiothoracic systems (e.g., carotid bruits), were all "amplified" in the acoustic mode. But when switched over to the Doppler setting, the clinicians still commented on their ability to hear related sounds associated with “murmurs” and “flow of blood” across a stenotic artery. These findings suggest a confidence that if an abnormal sound was detected by a clinician then he/she would be able to continue to medically manage the patient.

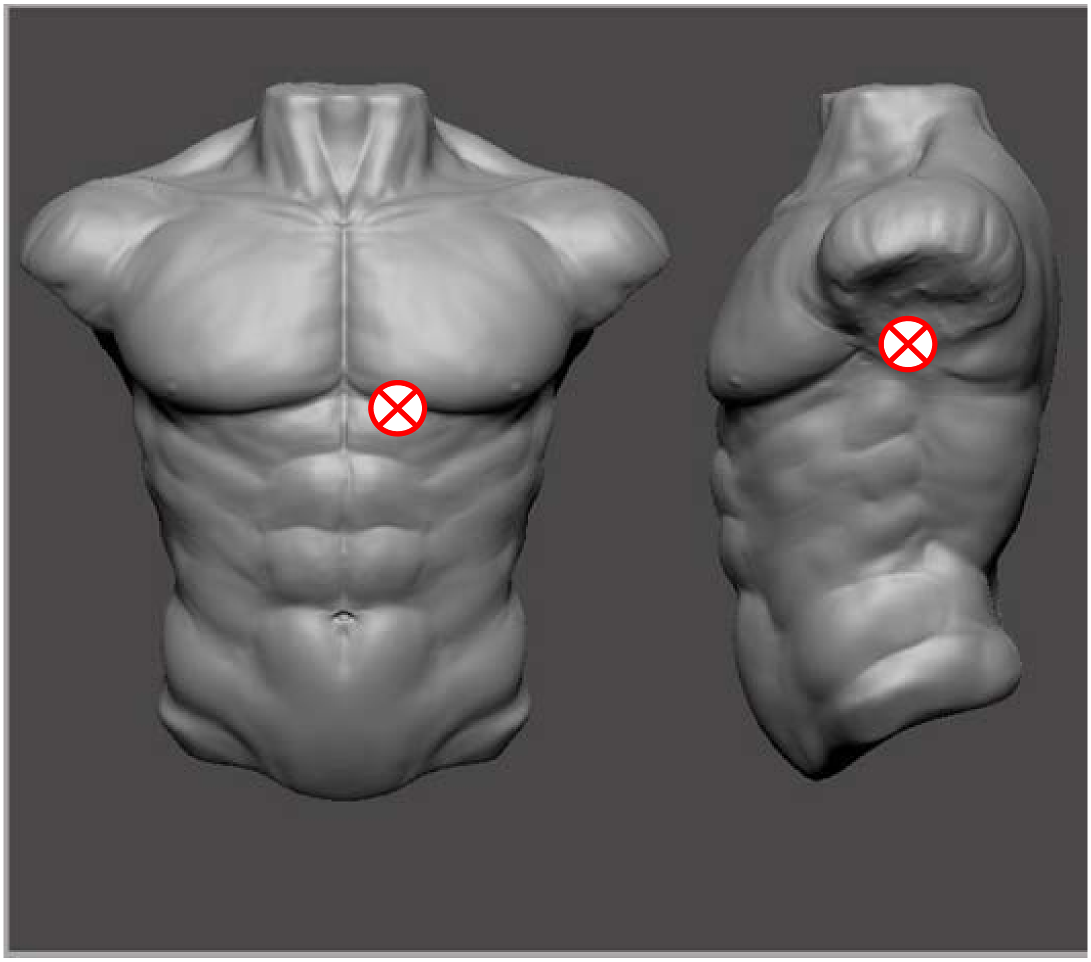

Figure 12. Ideal NIS placement on the body

Whether listening via acoustic or Doppler mode, patient physique also had an impact in the ease of use and confidence associated with using the NIS. Identifying cardiac/heart sounds and respirations/lung movement was easy in thinner patients, i.e., ectomorphs (figure 13). In contrast, the heavier patients, i.e. endomorphs, made it more challenging to identify respirations/lung movement. Palpable landmarks such as the ribs were not easily identifiable through tactile manipulation and took more time and gel. It became necessary to switch between acoustic and Doppler periodically to correctly recognize true lung movement from falsely generated Doppler sounds created by the friction of the device when placed on the surface of the body. As for those who were identified as mesomorphs, this was typically the active duty population and retired veterans. Placement of the NIS on the ectomorph and mesomorph body types was not difficult. The NIS is ideal for detecting cardiac rhythm and respirations in ectomorphs and mesomorphs, but more challenging when assessing those same cardiac and pulmonary sounds with endomorphs.

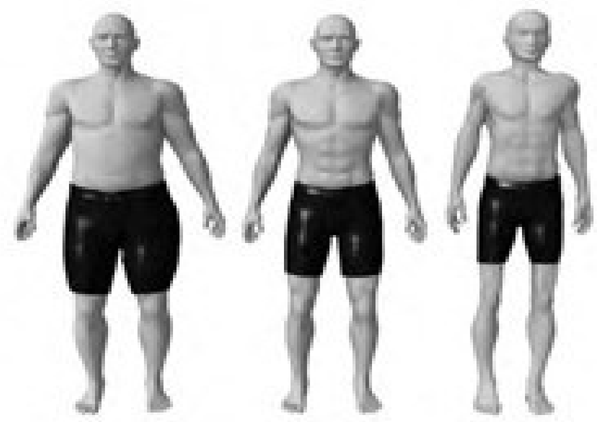

Figure 13. Body types

When using the NIS on all body types, there are three steps one should consider in order to maximize efficiency and confidence. First, there are two ideal physical locations on the body that improve clinicians' ability to hear cardiac sounds or respirations within the pulmonic region of the thoracic cavity as highlighted in the instructional DVD (Chapter: How Does the Stethoscope Work). Second, one should identify the appropriate heart sound or lung movement first in the acoustic mode on the patient. Third, one should then switch to the ultrasound Doppler (active) mode. This process is effortless and having the NIS easily switch between acoustic and Doppler modes will give the clinician a better appreciation to the specific heart rhythm or respiration sounds being identified on the patient.

As stated in the DVD, the NIS is designed to identify heart sounds and lung movement in high noise environments. However, clinicians want the sounds translated to more accustomed sounds to effectively manage patients.

Limitations

There were several limitations in this study. First, there were no intubations to determine the ease of use or confidence in applying the NIS. Second, there were a limited number of cardiac and pulmonary cases that were used to determine the capabilities and limitations of the NIS. For example, only four clinicians of the 15 initially enrolled in the study made observations using the NIS (n = 3 clinicians and n = 1 nurse practitioner). The remaining enrolled clinicians (n = 11) were not able to participate due to other hospital and unexpected patient requirements. Third, training was limited to only the DVD and the clinicians who wanted to be a part of the study felt that the DVD took too much time in explaining how to use the NIS.

Future directions

Future research should entail identifying and cataloging sounds heard with a traditional stethoscope as compared to the acoustic and ultrasound Doppler modes of the NIS. Equating the sounds heard with a wide range of cardiopulmonary pathology will help to limit varied interpretation of cardiac and pulmonary sounds and standardize a set of sounds to train clinicians. Secondly, continued research that identifies common cardiac and pulmonary pathology amongst different body physiques will assist in determining trends observed from using the NIS. A critical part of being successful with the NIS is correct placement on the patient's body, and optimal location may be different amongst the varied physiques. Lastly, support from medical treatment facilities with patients presenting with a diversity of pathophysiology will continue to advance this line of research.

Conclusion

In low noise conditions, clinicians evaluated the NIS as moderately helpful in making future clinical diagnoses and decisions when compared to a traditional stethoscope. However, further research is still needed to understand and interpret the Doppler-generated sounds given the wide variety of cardiopulmonary pathology in large hospitals and medical centers.

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Appendix A.

Technical specifications, Noise Immune Stethoscope.

BACKGROUND: A stethoscope is one of the few diagnostic tools available to emergency medical personnel far-forward in the battlefield or in the civilian pre-hospital environment. However, the ability to hear subtle physiological sounds (auscultation) and detect life threatening conditions is frequently compromised by competing noises and commotion at the scene of injury or aboard medical transports.

PRINCIPLES OF OPERATION: Active Signal's stethoscope combats noise intrusion through use of two modes of operation depending on the intensity of background noise:

1. In the presence of relatively benign ambient noise (loud accident scenes, ambulances, emergency rooms, civilian Medevac helicopters, etc.) the device is configured as an amplified electronic stethoscope employing a passive piezoelectric sensor. Noise rejection is imparted by design of the piezoelectric element and mass of the housing.

2. When the ambient sound levels exceed the passive sensing limit, an active Doppler mode is engaged. This transposes the detection of vital physiological sounds from the audio frequency range (used by conventional or electronic stethoscopes) where physiological sounds typically overlap the background noise and hence are swamped out, to ultrasound which puts the measurement into an entirely different frequency band.

DEVICE CONFIGURATION: The dual mode stethoscope design is shown in Figure 1. The top section of the device is the battery compartment, which contains two 1.5V AA-cells. The device is held between the index and middle fingers, with the thumb free to operate a 4-button control panel shown in Figure 2. The bottom section contains the stethoscope sensors and signal-processing electronics. For operation as a passive amplified electronic stethoscope (Mode 1, above), a tall column of piezoelectric ceramic material is used as the sensing element (see Figure 3) contacting the center of the front face. At the top, this column is pressed against the stethoscope's casing. For the active ultrasound-Doppler mode of operation (Mode 2, above), two semicircle-shaped disks, made of piezoelectric material, are embedded in the sensor head, where one functions as a transmitting and the other as a receiving transducer. Details of the mounting geometry, the gap size between the discs and the gap orientation, and also the carrier frequency, determine the width of the sound beam and its penetration depth.

A thumb-operated 4-button control panel allows the device to be turned on (press any button), the signal volume to be set (+ and – buttons in the horizontal plane), and the operating mode to be selected (ultrasound or mechanical). This allows the user to switch between modes during auscultation of a patient without moving the stethoscope on the body.

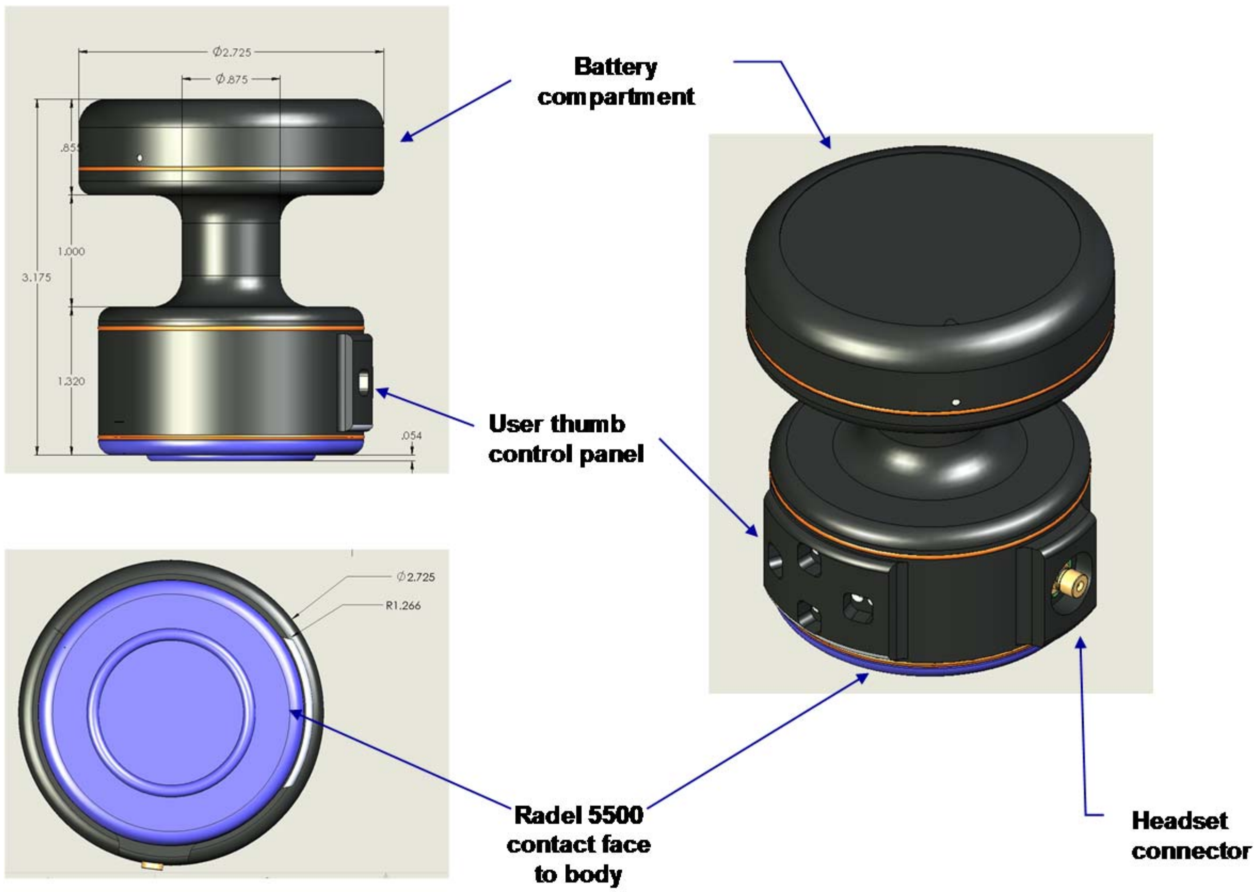

Figure 1. Dual-mode stethoscope design.

Figure 2. Four button control panel for changing mode and volume.

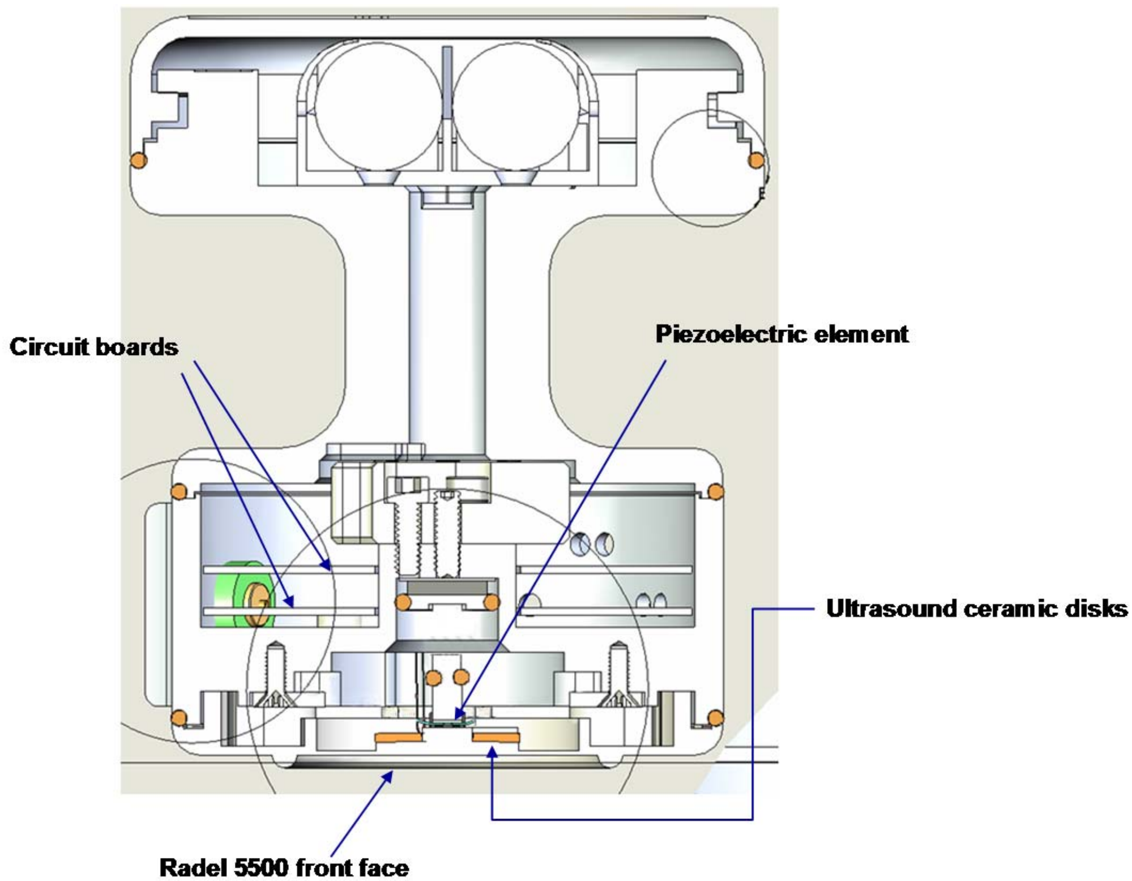

Figure 3. Details of sensor configuration and location of electronic boards.

FEATURES:

Dual 32 step digital volume controls with memory. This allows a comfortable listening level to be set in both modes by the user. Subsequent switching between modes can then be accomplished with minimal user adjustment to allow rapid comparison of acoustic and Doppler auscultation

High efficiency switching power supply and class D audio power amplifier. This extends useful battery life

Auto power off. Enters sleep mode after approximately 10 minutes of user control inactivity

Powered by two AA alkaline batteries.

Simple push button user controls.

Volume Up ↑

Volume Down ↑

Doppler mode button: has 2 functions →

With power off the Doppler mode button switches Power ON

With power on the Doppler mode button selects Doppler Mode

Acoustic mode button: has 2 functions →

With power off the Acoustic mode button switches Power ON

With power on the Acoustic mode button selects Acoustic Mode

SPECIFICATIONS:

Physical dimensions:

Weight: 340 grams (0.75 lb) (including batteries)

Height: 3.2 inches

Diameter: 2.7 inches (largest dimension)

Electrical Specifications:

Typical continuous operation battery life:

Power Off ~9,500 hours (~1 year)

Acoustic mode ~130 hours (~5 days) (minimal audio output)

Doppler mode ~48 hours (~2 days) (minimal audio output)

Audio power amplifier:

Power: 1.4 Watt into 8 Ohm load

THD: 0.19% (typical @ 0.5W)

Efficiency: 84% @ 400 mW

Frequency response: 5 Hz – 20 kHz

Connector: SMB

Doppler Frequency: 1.9 – 2.2 MHz

SIMILARITY TO EXISTING MEDICAL DEVICES: In the passive mode (piezoelectric sensor) the device operates in a similar way to many other amplified electronic stethoscopes on the market today. Acoustic information from physiologic processes is sensed as vibration energy at the surface of the body, converted to very low amplitude electrical signals by the piezoelectric ceramic, amplified with low noise electronics and transmitted electrically to speakers in the headset. Similarly, the Doppler mode employs substantially the same technology as widely available fetal heart rate monitors for the consumer market. Comparable to other devices that combine acoustic and Doppler modes, the Active Signal device combines the two modes in a compact and convenient self-contained package.

<u>Appendix B.</u>

<u>Data collection forms.</u>

INSTRUCTIONS

1. Complete: **OPERATOR INFO** below, *page 1* (Note: You ***MUST*** be a consented subject-clinician to operate the NIS stethoscope.)

2. Complete: **PATIENT DEMOGRAPHICS** (*page 1)* (Note: Patient ***MUST*** be consented.)

3. Complete: **INTUBATION INTEGRITY** (*page 2)*

or

HEMO/PNEUMOTHORAX (*page 3)*

or

ADVENTITIOUS OR PATHOLOGIC HEART/LUNG SOUNDS *(page 4)*

4. Complete: **NIS GENERAL COMMENTS & OBSERVATIONS** (*page 5)*

****

STETHOSCOPE OPERATOR INFO

Your Numeric Code (no names): _________ Date of data collection/observation: ____________

(**circle one**) Physician PA/NP Nurse Tech/Medic/Corpsman Other: ____________

(if Physician, **circle one**) Staff/Attending Fellow Resident

(if Physician, **circle one for specialty**)

Flight Surgeon Family Practice Internal Medicine Anesthesia Surgeon Other: ____________

Location (**circle**): EMS/ambulance ER General Ward Clinic ICU Other: ___________

Informed consent conducted to patient serving as the physiologic signal source (**circle**): Y N

****

PATIENT DEMOGRAPHICS

(Note: Do ***NOT*** include name, DOB, SSN, or any identifying information.)

Sex (**circle**): M F Age: _____ yrs.

****

INTUBATION INTEGRITY – *TRACHEAL* INTUBATION

Rate your ability to auscultate **BREATH sounds** bilaterally to confirm ET placement (score 1-7)?

ACOUSTIC Mode: **(POOR)** 1 2 3 4 5 6 7 **(EXCELLENT)**

DOPPLER Mode: **(POOR)** 1 2 3 4 5 6 7 **(EXCELLENT)**

Overall, rate your confidence to use this device to make correct diagnosis of intubation integrity ***compared to a traditional stethoscope*** (4=equivalent)

ACOUSTIC Mode: **(WORSE)** 1 2 3 EQUIV 5 6 7 **(BETTER)**

DOPPLER Mode: **(WORSE)** 1 2 3 EQUIV 5 6 7 **(BETTER)**

Tracheal intubation diagnosis was made/confirmed by (**circle all that apply**):

DL visualization traditional stethoscope capnography x-ray other: ____________

Mechanism of injury or etiology of medical condition: _________________________________

Notes: ____

____

Proceed to end of form for general comments.

****

INTUBATION INTEGRITY – *ESOPHAGEAL* INTUBATION

Rate your ability to auscultate **GASTRIC sounds** bilaterally to confirm ET placement (score 1-7)?

ACOUSTIC Mode: **(POOR)** 1 2 3 4 5 6 7 **(EXCELLENT)**

DOPPLER Mode: **(POOR)** 1 2 3 4 5 6 7 **(EXCELLENT)**

Rate your ability to auscultate ***NO*** **BREATH sounds** to confirm ET placement (score 1-7)?

ACOUSTIC Mode: **(POOR)** 1 2 3 4 5 6 7 **(EXCELLENT)**

DOPPLER Mode: **(POOR)** 1 2 3 4 5 6 7 **(EXCELLENT)**

Overall, rate your confidence to use this device to make correct diagnosis of esophageal intubation ***compared to a traditional stethoscope*** (4=equivalent):

ACOUSTIC Mode: **(WORSE)** 1 2 3 EQUIV 5 6 7 **(BETTER)**

DOPPLER Mode: **(WORSE)** 1 2 3 EQUIV 5 6 7 **(BETTER)**

Esophageal intubation diagnosis was made/confirmed by (**circle all that apply**):

DL visualization traditional stethoscope capnography x-ray other: ____________

Mechanism of injury or etiology of medical condition: _________________________________

Notes: ____

____

Proceed to end of form for general comments.

HEMO/PNEUMOTHORAX

Rate your ability to auscultate **decreased or absent BREATH sounds** as compared to the contra-lateral side for suspected diagnosis of hemo/pneumothorax (score 1-7)?

ACOUSTIC Mode: **(POOR)** 1 2 3 4 5 6 7 **(EXCELLENT)**

DOPPLER Mode: **(POOR)** 1 2 3 4 5 6 7 **(EXCELLENT)**

Overall, rate your confidence to use this device to make correct diagnosis of hemo/pneumothorax ***compared to a traditional stethoscope*** (4=equivalent):

ACOUSTIC Mode: **(WORSE)** 1 2 3 EQUIV 5 6 7 **(BETTER)**

DOPPLER Mode: **(WORSE)** 1 2 3 EQUIV 5 6 7 **(BETTER)**

Actual diagnosis (be as specific as possible [e.g., 25% simple left pneumothorax without rib fracture or other injuries]; if condition was suspected but not found, then so state [e.g., normal]):____

____

____

Diagnosis was made/confirmed by (**circle all that apply**):

traditional stethoscope CXR CT tube thoracostomy other: ____________

Mechanism of injury or etiology of medical condition: _________________________________

Notes: ____

____

Proceed to end of form for general comments.

ADVENTITIOUS OR PATHOLOGIC HEART/LUNG SOUNDS

Actual/known subject diagnosis (**circle**):

Valvulopathy: AI/AR AS PR PS VSD

MI/MR MS MVP TI/TR TS

Cardiomyopathy: ischemic dilated hypertrophic restrictive

Pulmonary disease: acute asthma pneumonia CHF emphysema

Other: ____

Diagnosis was made/confirmed by (**circle all that apply**):

traditional stethoscope CXR CT MRI cardiac cath

formal ultrasound informal/bedside ultrasound (e.g. Sonosite)

Other: ____

Mechanism of injury or etiology of medical condition: ________________________________

Overall, rate your confidence to use this device to hear the adventitious or pathologic sound (e.g. S3, S4, murmur, click, gallop, snap, wheeze, rales, rhonchi, bruit, etc.) and make correct diagnosis (or suspicion) of the known diagnosis ***compared to a traditional stethoscope*** (4=equivalent):

ACOUSTIC Mode: **(WORSE)** 1 2 3 EQUIV 5 6 7 **(BETTER)**

DOPPLER Mode: **(WORSE)** 1 2 3 EQUIV 5 6 7 **(BETTER)**

Describe in detail any ***novel or unique sounds*** that you are able to hear in Doppler mode (compared to a traditional stethoscope) for this medical condition: ________________________

____

____

____

Can you correlate these novel or unique sounds with findings from other diagnostic modalities (e.g., ultrasound)? ____

____

____

Notes: ____

____

Proceed to end of form for general comments.

NIS GENERAL COMMENTS & OBSERVATIONS

Overall, rate your *impressions of **ease of use*** of this device *compared to a traditional stethoscope* (4=equivalent):

ACOUSTIC Mode: (DIFFICULT) 1 2 3 EQUIV 5 6 7 **(EASY)**

DOPPLER Mode: (DIFFICULT) 1 2 3 EQUIV 5 6 7 **(EASY)**

Based on your use of the device, rate your *impressions of the **necessity for training*** (score 1-7):

I can learn to use this device on my own: **(NO)** 1 2 3 4 5 6 7 **(YES)**

This device should come with a teaching CD: **(NO)** 1 2 3 4 5 6 7 **(YES)**

This device requires "hands-on" training with an instructor: **(NO)** 1 2 3 4 5 6 7 **(YES)**

Rate how obtrusive or problematic you found the ***requirement of ultrasound gel*** in the Doppler mode: **(PROBLEM)** 1 2 3 4 5 6 7 **(EASY)**

This device has demonstrated the ability to preserve heart and breath sounds in high noise conditions using healthy volunteers (acoustic mode~90 dB, Doppler mode~110 dB). Based on your experience, to what degree to you feel this device ***could help you make clinical diagnoses and decisions*** in noisy environments (e.g., onboard a medical evacuation helicopter)?

(NOT HELPFUL) 1 2 3 4 5 6 7 **(HELPFUL)**

Do you have any recommendations for improvement in the design or function of the NIS?_____

____

____

Notes: ____

____

____

____

Appendix C.

Comments provided regarding heart/lung sounds.

Diagnosis	Comments
Aortic stenosis	“able to hear murmur”
Aortic stenosis	“rumbling friction with systole”
Aortic stenosis	“unable to understand Doppler”
Congestive heart failure	“able to hear crackles”
Aortic stenosis	“similar to traditional stethoscope, able to hear flows across stenosis”
Pneumonia	“where I heard crackles with my traditional stethoscope and the acoustic mode, I heard deep rumbling like thunder on Doppler”
Aortic stenosis	“able to hear clicks well”
Emphysema	“breath sounds on Doppler sounded like white noise even after repositioning”
Pneumonia	“able to hear rhonchi with good results”
Congestive heart failure	“able to hear extra noises (crackle) with Doppler easily”

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